

### REMARKS

The Office Action mailed November 10, 2005 (henceforth referred to as the "Office Action") rejected claim 43 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention.

With regard to the prior art, the Office Action rejected claims 23-25, 32, 35, and 44 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,007,903 to Ellard (henceforth, "Ellard"). The Office Action also rejected claims 23, 26, and 33-34 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,836,921 to Mahurkar (henceforth, "Mahurkar"). Further, claims 37-42 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 3,636,940 to Gravlee (henceforth, "Gravlee"). Additionally, claims 27-28 and 31 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Ellard in view of U.S. Patent No. 5,494,044 to Sundberg (henceforth, "Sundberg"). Finally, claims 29, 30, and 36 were independently rejected by the Office Action under 35 U.S.C. § 103(a) as allegedly being unpatentable over Ellard and Sundberg in further view of U.S. Patent No. 4,265,249 to Schindler al. (henceforth, "Shindler"), U.S. Patent No. 5,238,003 to Baidwan et al. (henceforth, "Baidwan"), and U.S. Patent No. 5,738,109 to Parasher (henceforth, "Parasher"), respectively.

In the present Response and Amendment, claims 23, 34, 37, and 42-43 have been amended. These amendments to the claims have been introduced to correct typographical errors, to address formality issues raised by the Office Action, and to otherwise refine the claims to place the present application in better condition for allowance and/or appeal.

No new matter has been introduced by any of these amendments. Reconsideration in view of the above amendments and following remarks is respectfully requested.

### Telephonic Interview

Applicant thanks Examiner Towa for extending the courtesy of speaking with Applicant's representative by telephone in advance of the filing of the present Response and Amendment. It is respectfully submitted that the present Response and Amendment brings the present

application in to alignment with the substance of the interview.

#### Claim Rejections

Each of the grounds for claim rejections are addressed below.

#### 35 U.S.C. § 112, second paragraph

Claim 43 was rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Applicant has by the amendments above corrected this claim in a manner that obviates all rejections under section 112. Reconsideration of these claims and removal of the rejections based upon section 112 are thus respectfully requested.

#### 35 U.S.C. § 102(b)

All claims stand rejected based upon the prior art for the reasons outlined above. Insofar as this ground for rejection applies to the claims as originally presented and as currently amended, Applicant respectfully traverses.

Applicant's prior Amendment dated August 31, 2005 made several arguments that were deemed unpersuasive by the Office Action. Applicant noted that Applicant's claims as previously presented were allowable over both Ellard and Mahurkar because those references failed to disclose a device that comprises "a flexible, hollow, and elongate catheter" as was recited in all pending claims. Rather, these two prior art references taught devices having retractable hollow needles that, in Applicant's opinion, are not flexible catheters as required by the claims. In particular, the remarks contained in that prior Amendment stated:

The difference between the flexible, hollow, elongate catheter as called for in claim 23 and the hollow need disclosed by Ellard and Mahurkar is very significant. The fact that the catheter of the device of the present invention is flexible and elongate is important in that it enables the catheter to follow the internal conformation of an internal cavity of a mammal when the device is

used for collection of a fluid sample from such an internal cavity for example, where a fluid sample is to be collected from the uterus of a human female the catheter must follow a curved path as it extends into the cavity. Accordingly, it is absolutely important and essential that the catheter be flexible. In addition, it is equally important the catheter is not a rigid device such as a hollow needle since a hollow needle or a similar device would be likely to puncture the wall of the uterus or other internal cavity (particularly if the rigid device was also sharp as in a needle).

In response to these remarks, the Office Action reasserted its position in rejecting the claims based on the premise that the term “flexible” as used in Applicant’s claims could be construed broadly to embrace a needle. In particular, the Office Action noted:

“The Examiner notes that the claim language only requires a flexible, hollow, elongate catheter. In response to applicant’s argument that the references fail to show certain features of Applicant’s invention, it is noted that the features upon which Applicant relies (i.e. that the flexible, hollow, catheter be capable of following the internal conformation of an internal cavity of a mammal) are not recited in the rejected claim(s). ... Examiner notes that none of [the dictionary] definitions require the term ‘flexible’ to mean capable of tracking a curved path or conformation.”

While Applicant disagrees with the Office Action’s conclusion that the terms “flexible” and “catheter” as recited in all of Applicant’s claims, when read together by one skilled in the relevant art, would not distinguish over a metal needle, the independent claims have all been amended herein to conform the claim language explicitly with Applicant’s definition of the term “flexible” as it is used throughout the specification (and as specifically argued by Applicant previously). Support for these claim amendments that make this feature explicit in the claims is found throughout Applicant’s specification, including, for example, within Example 1 which

begins at page 10, line 12. As such, it is submitted that the prior art rejections based upon Ellard and Mahurkar are improper for the reasoning set forth in detail in Applicants prior paper. Namely, neither Ellard or Mahurkar, alone or taken together, disclose, teach or suggest a device having a flexible, hollow and elongate catheter as presently claimed.

With regard to the rejections of independent method claims 37 and 42 based upon the Gravlee reference, it is Applicant's belief that the Examiner has misunderstood how the limitations of those claims distinguish over the prior art. In particular, claims 37 and 42 as presently amended both recite similar limitations that, in pertinent part, describe how in the claimed methods the catheter is flexible and follows the conformation of the internal cavity when the catheter is penetrating the cavity and also when the catheter is retracting from the cavity. Despite the Office Action's assertion to the contrary, the bare contention that Gravlee's device could somehow be flexible (the Office Action assumes improperly that all plastics are flexible which is a complete fallacy) does not teach one skilled in the art the Applicant's claimed invention.

Additionally, even if Gravlee disclosed a flexible catheter as claimed by Applicant, it still does not disclose the method steps of:

- 1) penetrating into the internal cavity by moving the catheter into the cavity while simultaneously passing wash fluid through the hollow catheter to wash at least a portion of the surface of the internal cavity; and
- 2) subsequently (i.e., after the penetrating step) retracting the catheter from the cavity while simultaneously collecting a fluid sample by aspirating the wash fluid through the hollow catheter.

These two separate steps (as indicated by the use of the language "subsequently" in the claim) as recited in claim 37 and, with similar language, in claim 42 are important features of the invention as they enable a good wash of the length of the cavity while also allowing for improved aspiration of fluid sample from the cavity. According to Applicant's claims, the catheter penetrates the cavity and simultaneously emits wash fluid as it penetrates into the cavity during

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the penetrating. The second, subsequent step as recited in Applicant's claims has the catheter retracting from the cavity and simultaneously aspirating wash fluid as it retracts from the cavity. The Office Action apparently has confused Applicant's claims and prior remarks to somehow be alleging that Gravlee doesn't disclose the simultaneous washing and aspirating of fluid. Clearly, this is not what the Applicant has claimed. The Applicant has described and claimed two steps regarding the penetration and retraction of the catheter into/from the cavity that are performed in succession. The catheter penetration step is synchronized with simultaneous emitting of wash fluid, while the subsequent catheter retraction step is synchronized with simultaneous aspirating of the previously emitted wash fluid. Neither of these two steps are disclosed, taught, or otherwise suggested by Gravlee.

Thus, all currently pending claims are presently allowable over the prior art.

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**Conclusion**

In view of the foregoing, the Applicant respectfully requests that the Examiner consider the claims as amended for examination on the merits. A timely allowance of the pending claims is requested.

Applicant has transmitted this Response and Amendment concurrently with a transmittal document serving as a Petition for Extension of Time for two months, and a check for the amount of the fee believed due in conjunction with that that Petition. If the appropriate fee amount has not been identified and specifically submitted with the Petition for Extension of Time, please charge any additional fees or credit any overpayments to Deposit Account No. 50-1349. Applicant has not herein increased the number of claims beyond the amount for which "additional claims fees" have been previously paid. Therefore, the check enclosed herewith does not include any amount intended to cover any additional claims fees. If, however, the appropriate amount has not been specifically submitted in that check, please charge any additional fees or credit any overpayments to Deposit Account No. 50-1349.


If there are any other fees due in connection with the filing of this Response, please charge any necessary fees to Deposit Account No. 50-1349.

The Examiner is specifically invited to contact Applicants' undersigned attorneys by telephone to discuss the present claims if the Examiner would like to discuss additional claim language that would allow the present application to go toward immediate allowance.

Respectfully submitted,

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